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The goals of this study are: 1) to examine the impact of a psychoeducational intervention on the intermediate outcome variables of knowledge of breast cancer and risk factors, breast cancer beliefs, cancer attitudes, and coping skills in women at increased risk for breast cancer; 2) to examine the impact of a psychoeducational intervention on the endpoint variables of quality of life and adherence to screening in women at increased risk for breast cancer; and 3) to explore the mechanisms by which the psychological intervention may improve quality of life and increase adherence to breast cancer screening in women at increased risk for breast cancer. The design is a randomized two group design in which women are assigned to either the experimental or control group. The intervention (experimental) components include; social support enhancement, education, cognitive restructuring, and problem-solving. A total of 360 are expected to participate in this study over a four year period of time. To date 183 women have agreed to participate in the study and 108 have completed Time 1 assessments, 96 have completed Time 2 assessments; 90 women have completed Time 3 assessments, and 77 women have completed Time 4 assessments. Preliminary data indicate that the women in the treatment arm have less breast cancer anxiety, are more knowledgeable about breast cancer, and have a lower perception of risk than women in the control arm at Time 2.

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Kathryn M. Kask PhD 20 October 1996

PI - Signature Date

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V. INTRODUCTION

a. Nature of the problem.

With the increased media attention focused on the importance of the early detection of breast cancer, more women were beginning to recognize the need for breast cancer screening and to look for places (programs, clinics, doctors) where they could obtain quality breast care. As women learn about their family history of breast cancer, they begin to speculate about their own risk. In addition, many women have heard that there is a gene (BRCA1) responsible for a small portion of breast cancer cases that was cloned last year. Already these women are requesting genetic testing as soon as it is available on a clinical level. We need to think about the psychological consequences for these women, as well as the ethical implications. Without adequate information, many women overestimate their risk and become quite fearful that they too could develop breast cancer. Our previous study identified anxiety as predictive of poor adherence to both clinical breast examinations and breast self-examination, as well as delay in having a mammogram (Kash et al, 1992). Thus adherence to breast cancer screening poses a major problem for women at increased risk who need timely screening. The emotional distress may also diminish a woman's quality of life, if the fear of developing breast cancer interferes with goal directed behaviors and problem solving activities. This information compelled us to intercede with women at increased risk for breast cancer and develop an intervention that could help to improve quality of life and increase adherence to breast cancer screening. Since women at increased risk increasingly identify themselves and look for programs where they can not only find out appropriate surveillance guidelines but share their feelings and concerns with others, the efficacy of a group intervention needed to be tested in a controlled trial. This study was designed to examine the role of such an intervention in improving quality of life and increasing adherence to screening behaviors (mammogram, breast self-examination, clinical breast examination). Our previous work, described below, piloted this intervention and found it to be extremely helpful to women in decreasing risk perception and increasing adherence to screening.

b. Background of previous work

Prior to the grant proposal, we conducted preliminary work on piloting a group psychoeducational intervention. There were three important components to this six week, structured intervention. The first was educating women: a) providing their objective risk status by giving them their own family tree (pedigree), b) clarifying information about breast cancer and risk factors for breast cancer; c) providing information on ways to take control of their lifestyle by changing their eating patterns; d) instructions on breast self-examination using both active and passive methods; and e) reinforcing the importance of adherence to screening guidelines. The second component revolved around cognitive restructuring, which helps to facilitate problem-solving. That is, we encouraged women to use active coping rather than avoidance or denial in dealing with their risk status. In addition, changing cognitions can help to alleviate anxiety and the sense of helplessness. The last component was that of emotional support which helped: a) to decrease the sense of isolation; b) to encourage sharing feelings and thoughts with others; and c) to provide reassurance by and rapport with other women.

In the pilot group ten women were randomly chosen from a group of 100 who responded affirmatively to participating in a group. These ten women completed baseline and six-week assessments. Perceived susceptibility for developing breast cancer significantly decreased ($p < .02$) on paired t-tests during the six weeks and approximated their actual risk, based on risk analysis tables. All of the women reported that their knowledge of breast cancer increased and

misconceptions were clarified. Anxiety and fears about developing breast cancer and its consequences were diminished in 90% of these women. Thirty percent who had never performed BSE began to do so and expressed their intent to perform it monthly. Women felt that the emotional support provided by the group was extremely important, as well as the opportunity to exchange feelings and information with women facing the same problems who coped with them daily, using a range of strategies. At a two month follow-up session, all women reported performing monthly BSE. At six months, one year, two years, and three years, there was 90% adherence to mammogram schedule and CBE; 100% were performing BSE monthly. Seventy-five percent of women also reported using the information from the dietician to reduce their fat intake (Kash, 1991).

Using the information from the above mentioned pilot group, we refined our intervention and developed a structured format for the group leader and session leaders to follow. We collected baseline data via a telephone questionnaire on 20 women and randomized them to either the intervention or control group. Analyses of variances on baseline data revealed no significant differences between the groups on any of the demographic, independent, or outcome variables. Within this model our goals were; to provide women with accurate and clear information on actual risk status, breast cancer, risk factors, methods of risk reduction (e.g., low fat diet), appropriate surveillance procedures; and help women learn how to actively cope with their risk. The group then met for six consecutive weeks. The structure and content of these sessions was similar to that of the pilot group and is described in the manual below.

At the end of the six week group intervention telephone assessments were conducted by a trained interviewer. The interviewer was blind as to which group the woman belonged. Within the intervention group there was a significant increase in knowledge ($p<.05$), a significant decrease in perceived risk or susceptibility ($p<.015$), and a significant decrease in perceived barriers to screening ($p<.05$) between baseline and six weeks (the end of the group). Analyses of variances at Time 2 revealed several changes between the groups: 1) a significant increase ($p<.005$) on knowledge of breast cancer in the experimental group; 2) a significant decrease ($p<.02$) on perceived barriers in the experimental group; and 3) a significant increase ($p<.03$) on knowledge of the risk factors for breast cancer in the experimental group. For example, at Time 2 there were still women in the control group (30%) who thought that being "hit in the breast" increased your chances of developing breast cancer. There were also significant differences between the two groups on perception of risk ($p<.001$) with only the experimental group accurately reporting their risk status. There were no differences between the groups on tension or depression at the end of six weeks. Our preliminary data was reported earlier this year (Kash et al, 1995).

c. Purpose of the present work

The purpose of this study is to address quality of life and adherence to screening issues associated with being at increased risk for breast cancer. The specific aims are:1) to examine the impact of a psychoeducational intervention on the intermediate outcome variables of knowledge of breast cancer and risk factors, breast cancer beliefs, cancer attitudes, and coping skills in women at increased risk for breast cancer; 2) to examine the impact of a psychoeducational intervention on the endpoint variables of quality of life and adherence to screening in women at increased risk for breast cancer; and 3) to explore the mechanisms by which the psychological intervention may improve quality of life and increase adherence to breast cancer screening in women at increased risk for breast cancer.

d. Methods of approach

The research design uses a randomized controlled trial to test the psychoeducational group intervention. The intervention components (as identified above) include; social support enhancement, education, cognitive restructuring, and problem-solving. A total sample size of 360 is sufficient to allow hypotheses testing. Data will be collected at four points in time; baseline, six weeks, six months, and one year. The variables to be examined are: demographic; risk status; selection method; stressful life events; knowledge of breast cancer and risk factors; breast cancer beliefs; cancer attitudes; coping strategies; quality of life (psychological distress, role, work and family functioning, life satisfaction, satisfaction with health care, and participant goal-directed behaviors); and adherence to CBE, mammogram, and BSE. Preliminary analyses include descriptive statistics, correlational, and principal components analysis. Multivariate analysis of variance with repeated measures and appropriate covariates will be used to test the hypotheses.

VI. PROGRESS REPORT

A. Experimental methods used

The medical and family histories for all women enrolled in the Strang Breast Surveillance Program are reviewed by Dr. Kash (PI) for eligibility to participate in the study. Women are classified as being at low (13 to 19%), moderate (20 to 34%), or high (35 to 50%) risk based on their family histories of breast and/or ovarian cancer (Claus et al, 1991). Examples of low risk are having a mother who developed breast cancer at the age of 40 or a mother who developed breast cancer at age 52 and a maternal grandmother who developed breast cancer at age 60. An example of moderate risk is having a mother, maternal grandmother, and a maternal aunt, all who developed breast cancer in their 50's. Some examples of high risk are: 1) having a mother, maternal grandmother, and three maternal aunts who developed breast cancer in their 40's or 50's; 2) having a mother who developed bilateral breast cancer in her 50's, a father with breast cancer at age 60, a paternal aunt with breast cancer at age 50, and a sister with breast cancer at age 38; or 3) having a mother who developed breast cancer in her 40's, a maternal grandmother who had ovarian cancer in her 50's, and a maternal cousin with bilateral breast cancer in her 40's.

Names of eligible women are randomly selected. Those women selected were sent a letter explaining the purpose and requirements of the study. Each woman who does not respond within a two week period were contacted by telephone by Ms. Hernandez (Research Associate) and told of the study project and exactly what is being asked of them. Ms. Caroline Moore took over the position of Research Associate as of October 1, 1996. It was explained to each woman that after baseline data was obtained they would be randomized to either the experimental (standard care plus an intervention group) or the control (standard care) condition. If the participant agreed, an informed consent was obtained from her prior to the beginning of the study. Part of the informed consent process was to obtain permission from the participants to audio tape record each session and video tape some sessions in order to conduct quality checks and make sure that the outline was adhered to for each session. Baseline data was obtained prior to randomization to either the experimental or control condition. Ms. Hernandez remained blind as to which group each woman belonged so as not to influence the interview process.

Prior to the beginning of each intervention group (a total of seven in the first two years), twenty women were randomly selected from the pool of available participants (total of 182 for the first seven groups). The assessment instrument was mailed to these twenty participants and a time set for the baseline assessment telephone interview (T1). After the baseline assessment women were

randomized to either the experimental and control condition. When the six session intervention group ended (T2), the assessment instrument was mailed to all participants and a telephone time set for the post-intervention interviews. A stamped, self-addressed envelope was mailed to the participant with the assessment instrument. Once the telephone interview was finished, the participant mailed the interview back so we could have a hard copy of the data.

Several measures were chosen to assess cognitive, psychological, and behavioral variables. The majority of these measures consist of structured questions and require about 30 minutes to complete. One of the Quality of Life measures, the Patient-Centered Methods, is semi-structured and takes about 20 minutes during the telephone interview, which is done after recording the responses to the structured measures. These measures are assessed at four points in time: T1 – baseline (prior to randomization); T2 – within one week after the six week intervention has ended; T3 – six months after the beginning of the intervention; and T4 – one year after the beginning of the intervention. The measures are listed below.

Measures used
Mammogram adherence
Clinical breast examination (CBE)
Breast self-examination (BSE)
Revised Rand General Well-Being Scale
Social Adjustment Scale-Self Report
Patient Satisfaction Subscales
Life Satisfaction Index
Patient-Centered Methods
Knowledge about Breast Cancer and Breast Cancer Screening
Breast Cancer Beliefs
Cancer Attitude Scales (Anxiety, Hopelessness, and Adjustment)
Coping Strategies
Sociodemographic information
Stressful Life Events
Risk status

B. Work to date as related to goals
1. In the Statement of Work (Appendix A) the five items in Task 1 have been accomplished. They are as follows.
a) All the materials to be used with those subjects in the experimental condition were ordered and received. They have been used in in each of the experimental groups conducted and will be ordered and used in each year.
b) All questionnaires to be used in this study were completed. Other paperwork, such as labels being generated, envelopes addressed, and questionnaires copied for distribution to subjects, was also completed.
c) The Quality of Life measures were finalized and included in the interview packet for subjects.
d) The psychoeducational intervention manual was completed.
e) The research assistant and the research associate were both trained on how to carry out their various responsibilities, which included, but was not limited to, patient contacts, interviewing subjects, and coding and entering data. The research assistant and the research associate resigned within the last three months. The research associate has been replaced; a research assistant should be in place by the end of January 1997.

The social worker initially hired resigned after five months as she had a physical injury that required treatment in another state. Subsequently we sought and obtained permission from the Department of the Army to hire another social worker as a consultant to carry out the rest of the four year study. To date, this social worker has conducted all the intervention groups.

2. In the Statement of Work the first two items in Task 2 have been completed as follows.
a) In the first wave, 170 women were contacted and asked to participate in the study. As anticipated 101 women agreed to participate in the study (59% response rate).
b) In the second wave, 200 women were contacted and asked to participate in the study. Only 82 women agreed to participate rather than the 120 women we anticipated (41% response rate). Women who declined participation cited their main reasons as; live too far away, can't make commitment to every week for six weeks, inconvenient time (would rather have it on weekends), feel they don't need support right now, and not interested in groups.
c) The third wave began in October 1996. We started contacting 300 women in order to obtain between 120 (40% response rate) and 180 (60% response rate) women for this wave.

3. In the Statement of Work all the items in Task 3 have been completed (or are ongoing) as scheduled.
a) For the first wave: after the initial interview, women were randomized to either the control (N=51) or experimental condition (N=50). Because we hired a new social worker to conduct the groups, they did not begin until the fifth month. Despite this initial delay we completed five groups in the first years as initially planned. The number of women who completed the control condition was 45 and the number who completed the experimental condition was 38. In the control condition, one woman was diagnosed with breast cancer after completing the first questionnaire and therefore withdrew from the study. The other five women in the control condition withdrew from the study because they did not want to complete any more questionnaires. In the experimental condition, 12 women did not continue after randomization or withdrew from the study: 1) one woman did not have a family history of breast cancer (unknown to us until randomized); 2) two women never showed up; 3) one woman had to postpone starting until January 1996 because of back surgery; 4) one woman had to postpone starting until January 1996 because of job commitments; 5) two women were unable to complete all the sessions related to outside issues; 6) one woman had breast cancer (unknown to us until randomized); and 7) the other four women withdrew after randomization and prior to the beginning of the groups.

For the second wave: after the initial interview, women were randomized to either the control (N=44) or experimental condition (N=38). The number of women who completed the control condition was 12 and the number who completed the experimental condition was 13. In the control condition, 32 women withdrew from the study after completing the initial questionnaire and randomization. One woman was diagnosed with breast cancer, two women moved away, four women never responded to any other questionnaires, and 25 women were no longer interested in participating because they were not in the treatment group. In the experimental condition, 25 women withdrew from the study after completing the initial questionnaire and randomization. One woman never showed up for the intervention, three women postponed until next year because of various other commitments, 10 women had to travel for their jobs and could not complete the six sessions, and 11 women stated that they had other work obligations and could not attend all six sessions. The work obligations included; new shift schedule, different work days, and unable to get out of work on time for group sessions.

b) The one year assessment has been completed for five groups (n=83) and the six month assessment has been conducted for two groups (N=25). Altogether we have data on 108 women at Time 1, 96 women at Time 2 (12 women did not complete Time 2), 90 women at Time 3 (still waiting for 18 women to complete the questionnaire), and 77 women at Time 4 (six women did not complete the questionnaire).
c) Data entry began in the seventh month. Table 1 lists the demographics of the participants in the study. Table 2 lists the risk levels and adherence to screening behaviors of the participants.

4. In the Statement of Work all the items in Task 4 have been completed (or are ongoing) as scheduled.
a) All five groups were completed in the first year as planned. Two groups out of six, that were planned, were completed in the second year.
b) The one year "booster" session was conducted for five groups and the six month "booster" session was conducted for two groups.
c) Dr. Paul Jacobsen, a consultant in behavioral medicine, has conducted quality checks on the consistency and accuracy of the content of the sessions by listening to the audio cassettes.

5. In the Statement of Work all the items in Task 5 have not begun and are not scheduled until month 44.

VII. CONCLUSIONS

This study as designed is being carried out according to the Statement of Work. This research project will take a total of four years to complete and will be examining effects over time. From our initial review of the demographics data (N=108) there are no differences between those assigned to the experimental or control conditions on the following variables: age, marital status, racial/ethnic background, highest grade completed, employment status, occupation, religion, income, number of children, or actual risk level.

We have done some preliminary analyses looking at coping strategies, breast cancer anxiety, risk perception, and knowledge of breast cancer. We found that women in the treatment arm had significantly: 1) less breast cancer specific anxiety at Time 2 ($p<.03$); 2) lower perception of risk at Time 2 ($p<.001$); and 3) greater knowledge of breast cancer at Time 2 ($p<.02$). In terms of coping strategies with stressful life events, we found that women in the treatment arm reported using more positive reframing (e.g., I've been looking for something good in what is happening), more active coping (e.g., I've been taking action to make the situation better), and more planning (e.g., I've been trying to come up with a strategy about what to do) than women in the control arm. While these data are very preliminary, they are very promising and support the goals of the study.

Anecdotal reports from women in the experimental condition indicate that they have obtained a tremendous amount of knowledge and feel less anxious about carrying out early detection behaviors for breast cancer. One woman in the treatment group, who came in on time for her mammogram, was told there were microcalcifications on her film and she needed to have a biopsy. When she was scheduling it with a breast surgeon she told me that she was not worried. In her words, "I came in right on time for a mammogram and a breast examination because I learned the importance of early detection in the [group] sessions. I'm not really anxious about the procedure or the outcome because my group asked questions about biopsies and I also know that most of these [mammogram findings] are benign. If it weren't for the group, I would not have come in when I was suppose to and I would be really nervous that I do have breast cancer."

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APPENDIX A

PSYCHOEDUCATIONAL GROUP INTERVENTION FOR WOMEN AT INCREASED RISK FOR BREAST CANCER

Task 1. Preparation of materials, intervention manual & training of staff– Months 1-3:

a. Materials to be used with experimental condition will be ordered.
b. Questionnaires copied, labels created, and envelopes addressed.
c. Quality of life measures are finalized.
d. The psychoeducational intervention manual will be completed.
e. The research assistant, research fellow, and the social worker will be trained in their various responsibilities.

Task 2. Randomization of sample and recruitment of participants– Months 3-36

a. Eligible women will be randomly sampled and recruited for participation. Recruitment for participation in this study will be done at one year intervals so that all the recruitment will not be done in the first year. In the first wave we will contact 170 women for the first year as we anticipate a 60% response rate and a need for 100 women.
b. Second wave of recruitment begins (month 12), 200 women will be contacted to insure that we have 120 women for study.
c. Third wave of recruitment begins (month 24), 200 women will be contacted to insure that we have 120 women for study.
d. Fourth wave of recruitment begins (month 36), 34 women will be contacted to insure that we have 20 for study.

Task 3. Assessments collected– Months 3-48:

a. Baseline assessments are collected prior to randomization to experimental (N=180) or control (N=180) condition for a total of eighteen cycles (N=360), with new intervention groups (experimental condition) starting every two months beginning in the third month (months 3-36).
b. Six week, six month and one year assessments are collected on those in the experimental (intervention group) and control conditions.
c. Data entry begins in month 5.

Task 4. Intervention groups and "booster" sessions conducted– Months 3-48:

a. An intervention group (experimental condition) begins every two months, starting in month 3 (5 in the first year, 6 in the second year, 6 in the third year, and 1 in the fourth year).
b. Six month and one year "booster" sessions are conducted for those in the experimental condition.
c. Quality checks on consistency and accuracy of content of sessions are performed through the use of audio and video tapes.

Task 5. Data analyses– Months 44-48:

a. Preliminary data analyses are begun in month 44.
b. Tests of differences between experimental and control conditions on several variables (e.g., age, referral source, prior screening behavior, psychological distress) are begun in month 44.
c. MANOVA and MANCOVA with repeated measures are performed starting in month 44.
d. Final analyses are completed in month 48.

APPENDIX B

Table 1. Demographics of study participants (N=108)

Age: range is from 24 to 76 years with a mean of 42 years

Variable	%
Marital Status	
Single or never married	35.6
Married or living as married	49.5
Separated or divorced	11.9
Widowed	3.0
Ethnic/Racial	
White	90.0
African American	4.0
Hispanic	5.0
Other	1.0
Grade	
High School or GED	6.0
Some college	12.9
College	37.6
Graduate school	37.6
Post-graduate school	5.9
Employment	
Full time	63.4
Part time	17.8
Retired	5.9
Homemaker	7.9
Disabled	1.0
Student	2.0
Unemployed	2.0
Religion	
Catholic	33.0
Jewish	39.0
Episcopalian	4.0
Protestant	3.0
Presbyterian	3.0
Baptist	2.0
None	10.0
Other	6.0
Children	
No	57.4
Yes	42.6

Table 2. Risk levels and screening behaviors of study participants (N=108)

Risk levels	%
Medical risk categories	
Low: 13 - 19%	27.8
Moderate: 20 -34%	33.3
High: 35-50%	38.9
Perception of risk of developing breast cancer	
Extremely likely	9.1
Very likely	30.3
Moderately likely	35.4
Somewhat likely	22.2
Not at all likely	3.0
Medical risk continuum	
13% to 50% based on family history	Mean = 31.07
Perception of risk of developing breast cancer (from 0% to 100%)	
4% to 100%	Mean = 51.82
Screening Behaviors	**%**
Breast self-examination (BSE)	
Yes	73.1
No	26.9
BSE-how often in the past six months	
from 0 to 48 times	Mean = 3 times
Clinical breast examination (ever had one)	
Yes	100
Mammogram (ever had one)	
Yes	92.6
No	7.4

APPENDIX C

SUBMITTED TO THE SOCIETY OF BEHAVIORAL MEDICINE FOR PRESENTATION AT ANNUAL MEETING IN APRIL 1997

IMPROVING QUALITY OF LIFE AND INCREASING ADHERENCE TO BREAST CANCER SCREENING IN WOMEN AT RISK

Kathryn M. Kash, Ph.D., Daniel G. Miller, M.D., Michael P. Osborne, M.D., Strang Cancer Prevention Center, Jimmie C. Holland, M.D., Memorial Sloan-Kettering Cancer Center

Previous research found that anxiety interfered with adherence to screening in women with family histories of breast cancer. A randomized controlled trial of a psychoeducational group intervention is being conducted. The specific aims are to examine the impact of the intervention on the: 1) intermediate outcome variables of knowledge of breast cancer and risk factors, breast cancer beliefs, breast cancer anxiety, and coping skills; and 2) endpoint variables of quality of life and adherence to screening. The intervention components include social support enhancement, education, cognitive restructuring, and problem-solving. Group sessions (8 to 10 women in each group) meet for one and a half hours each of six weeks, with six month and one year booster sessions. Interviews are conducted prior to randomization (Time 1), at the end of the six week intervention (Time 2), at six months (Time 3) and one year (Time 4).

To date 71 healthy, asymptomatic women at high risk for breast cancer (control condition N=31; experimental condition N=40) have participated in the study and have completed Time 1 and 2 assessments; 17 women have completed Time 3 assessments. The mean age is 43, primarily white (93%), with 38% having a college education. At baseline, 74% of women in both conditions overestimated their risk for developing breast cancer. Women in the experimental condition (65%) were more likely to use positive reframing, planning, and active coping in helping them adjust to their heightened breast cancer risk at Time 2. A t-test found a significant reduction in breast cancer specific anxiety within the experimental group from Time 1 to Time 2 ($p<.03$), as well as a decrease in perception of risk ($p<.001$). In addition, women in the experimental condition significantly improved their knowledge of breast cancer ($p<.02$). These findings suggest that the intervention helps to decrease anxiety and improve quality of life.